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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2636]

Guidance for Industry on Levothyroxine Sodium; Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Levothyroxine Sodium: Questions and Answers.'' The guidance is intended to answer questions concerning applications for orally administered levothyroxine sodium drug products.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

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I. Background

FDA is announcing the availability of a guidance for industry entitled ''Levothyroxine Sodium: Questions and Answers.'' In the **Federal Register** of August 18, 1999 (64 FR 44935), FDA announced the availability of a draft version of this guidance. The August 18, 1999, document gave interested persons 60 days to submit comments. FDA has revised the guidance in response to comments. Among the revisions being made is that FDA has extended the deadline for levothyroxine sodium drug products to have approved applications from August 14, 2000, to August 14, 2001. This extension was announced in the **Federal Register** on April 26, 2000 (65 FR 24488).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The guidance represents the agency's current thinking on issues concerning applications, including applications under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2)), for levothyroxine sodium. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/guidance/index.htm.

Dated: March 1, 2001
March 1, 2001.

Ann M. Witt,
Acting Associate Commissioner for Policy.

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